

DARICLOX- cloxacillin sodium suspension
Merck Sharp & Dohme Corp.

Dariclox®
(sodium cloxacillin)

F-27865500

LACTATING COW FORMULA
(FÓRMULA PARA VACAS LACTANTES)

Intramammary Infusion
(Infusión intramamaria)

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION: Dariclox (sodium cloxacillin) is a stable, nonirritating suspension of sodium cloxacillin containing the equivalent of 200 mg of cloxacillin in saturated vegetable oils per disposable syringe. Dariclox is manufactured by a nonsterilizing process.

Cloxacillin is a semisynthetic penicillin derived from the penicillin nucleus, 6-amino-penicillanic acid. Sodium cloxacillin is the monohydrate sodium salt of 5-methyl-3-(o-chlorophenyl)-4-isoxazoly penicillin.

ACTION: Sodium cloxacillin is bactericidal in action against susceptible organisms during the stage of active multiplication. It acts through the inhibition of biosynthesis of cell wall mucopeptide. It is active against most gram-positive organisms associated with mastitis. It is effective against *Streptococcus agalactiae* and nonpenicillinase-producing *Staphylococcus aureus*, and there is laboratory evidence that indicates cloxacillin is resistant to destruction by penicillinase-producing organisms. Milk cultures and antibiotic susceptibility testing is recommended when using this product.

SUSCEPTIBILITY TEST: The Kirby-Bauer¹ procedure, utilizing antibiotic susceptibility disks, is a quantitative method that may be adapted to determining the sensitivity of bacteria in milk to Dariclox.

For testing the effectiveness of Dariclox in milk, follow the Kirby- Bauer procedure using the 1 mcg oxacillin susceptibility disk. Zone diameters for interpreting susceptibility are:

Resistant	Intermediate	Susceptible
≤ 10 mm	11–12 mm	≥ 13 mm

¹ Bauer AW, Kirby WMM, Sherris JC, *et al*: Antibiotic testing by a standardized single disk method, *Am J Clin Path* 45:493, 1966. Standardized Disk Susceptibility Test, Federal Register 37:20527–29, 1972.

INDICATIONS: Dariclox is indicated in the treatment of bovine mastitis in lactating cows due to *Streptococcus agalactiae* and nonpenicillinase-producing *Staphylococcus aureus*.

Clinical experience indicates that antibiotic efficacy in the treatment of mastitis in lactating cows is directly related to the duration of infection. Therefore, treatment should be instituted as early as possible after detection.

WARNINGS: Milk taken from animals during treatment and for 48 hours (4 milkings) after the last treatment must not be used for food. Treated animals must not be slaughtered for food purposes within 10 days after the last treatment.

PRECAUTION: Because it is a derivative of 6-amino-penicillanic acid, Dariclox has the potential for producing allergic reactions. Such reactions are rare; however, should they occur, the subject should be treated with the usual agents (antihistamines, pressor amines).

DOSAGE AND ADMINISTRATION: Milk out udder completely. Wash udder and teats thoroughly with warm water containing a suitable dairy antiseptic. Dry thoroughly. Clean and disinfect the teat with alcohol swabs provided in the carton. Remove the syringe tip cover and insert the tip of the syringe into the teat orifice. Express the suspension into the quarter with gentle and continuous pressure. Withdraw the syringe and grasp the end of the teat firmly. Massage the medication up into the milk cistern.

For optimum response the drug should be administered by intramammary infusion in each infected quarter as described above. Treatment should be repeated at 12-hour intervals for a total of 3 doses. The treated quarter should be milked out at the next routine milking.

Each carton contains 12 alcohol swabs to facilitate proper cleaning and disinfecting of the teat orifice.

HOW SUPPLIED: Dariclox is supplied in cartons of 12 single-dose syringes with 12 alcohol swabs. Each 10-mL, disposable syringe contains sodium cloxacillin equivalent to 200 mg of cloxacillin.

Do Not Store Above 24°C (75°F)

NADA #55-070, Approved by FDA

Manufactured by:
G.C. Hanford Mfg. Co.
Syracuse, NY 13201



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PRINCIPAL DISPLAY PANEL - 12 Syringe Carton

Dariclox[®]
(sodium cloxacillin)

LACTATING COW FORMULA

Intramammary Infusion

short tip

48-HOUR MILKOUT

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**12 single-dose (10 mL),
disposable syringes**

NADA #55-070, Approved by FDA

Schering-Plough Animal Health Corp.

Dariclox[®]

(sodium cloxacillin)

LACTATING COW FORMULA
(FÓRMULA PARA VACAS LACTANTES)

Intramammary Infusion
(Infusión intramamaria)



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NADA #55-070, Approved by FDA



Schering-Plough Animal Health Corp.

Dariclox[®]

(sodium cloxacillin)

LACTATING COW FORMULA
(FÓRMULA PARA VACAS LACTANTES)

Intramammary Infusion
(Infusión intramamaria)



**DISCARD MILK FOR
48 HOURS AFTER
LAST TREATMENT**

READ RESIDUE WARNING



**DO NOT SLAUGHTER
COW FOR 10 DAYS AFTER
LAST TREATMENT**

F.P.O.
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Code
0483



Schering-Plough Animal Health Corp.





Dariclox[®]
(sodium cloxacillin)
LACTATING COW FORMULA
(FÓRMULA PARA VACAS
LACTANTES)
12 single-dose (10 mL),
disposable syringes

Schering-Plough Animal Health Corp.

Dariclox[®] (sodium cloxacillin)

LACTATING COW FORMULA (FÓRMULA PARA VACAS LACTANTES)

Description: Each 10-mL, single-dose, disposable syringe contains sodium cloxacillin equivalent to 200 mg of cloxacillin in a suitable base. Manufactured by a nonsterilizing process.

Indications: For the treatment of bovine mastitis in lactating cows due to *Streptococcus agalactiae* and nonpenicillinase-producing *Staphylococcus aureus*.

Dosage and Administration: After milking, clean and disinfect the teat with alcohol swabs provided in the carton. Remove the syringe tip cover and insert the tip of the syringe into the teat orifice. Express the suspension into the quarter with gentle and continuous pressure. Withdraw the syringe and grasp the end of the teat firmly. Massage the medication up into the milk cistern. Treatment should be repeated at 12-hour intervals for a total of 3 doses. The treated quarter should be milked out at the next routine milking.

➡ **Warnings:** Milk taken from animals during treatment and for 48 hours (4 milkings) after the last treatment must not be used for food. Treated animals must not be slaughtered for food purposes within 10 days after the last treatment. ⬅

Precaution: Administration of this product in any manner other than described under Dosage and Administration may result in drug residues.

Veterinary Use Only—Not for Human Use

Keep Out of Reach of Children

Discard Empty Container—Do Not Reuse

Do Not Store Above 24°C (75°F)

Read Insert for Complete Directions

Manufactured by:

TAKE TIME



OBSERVE LABEL
DIRECTIONS

Dariclox[®] (sodium cloxacillin)

LACTATING COW FORMULA (FÓRMULA PARA VACAS LACTANTES)

Intramammary Infusion (Infusión intramamaria)

48-HOUR MILKOUT

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**12 single-dose (10 mL),
disposable syringes**





DARICLOX

cloxacillin sodium suspension

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0061-6280
Route of Administration	INTRAMAMMARY		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Cloxacillin Sodium (UNII: 65LCB00B4Y) (Cloxacillin - UNII:O6X5QGC2VB)	Cloxacillin	200 mg in 10 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0061-6280-01	12 in 1 CARTON		
1		10 mL in 1 SYRINGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA055070	12/23/1977	

Labeler - Merck Sharp & Dohme Corp. (001317601)